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PATENT

Attorney Docket No.: 010692-004531US

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Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

By: Masha M. Martinenko  
Masha M. Martinenko

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Stephen R. Gorfine

Application No.: Not yet assigned  
Continuation of Application No.: 08/970,447

Filed: Herewith

For: NITRIC OXIDE DONOR  
COMPOSITION AND METHOD FOR  
TREATMENT OF ANAL DISORDERS

Examiner: Not yet assigned

Art Unit: Not yet assigned

PRELIMINARY AMENDMENT

Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

IN THE SPECIFICATION:

This application is a Continuation of U.S. Application No. 08/970,447 filed on June 29, 1999 which was a Continued Prosecution Application of U.S.

Application No. 08/970,447 filed on November 14, 1997 which was a Continuation of U.S. Application No. 08/666,264 filed on June 20, 1996, which was a Continuation of U.S. Application No. 08/371,088 filed on January 10, 1995, now abandoned, which was a Continuation-In-Part of U.S. Application No. 08/250,555 filed on May 27, 1994, now U.S. Patent No. 5,504,117. The disclosures of each of which are incorporated by reference.

IN THE CLAIMS:

Please cancel claims 1-36 without prejudice.

Please enter the following new claims:

--37. A kit for administering a unit dosage of a topical composition for treating an anorectal disease, said kit comprising,

multiple unit dosages of a semisolid pharmaceutical composition consisting essentially of a NO donor as the active ingredient in combination with a pharmaceutically acceptable carrier, wherein each unit dosage is accurate and controllable and has nitroglycerin in an amount effective for topical treatment of an anal disease within a range of from about 0.05 mg to about 1000 mg, and  
a container for storing and providing multiple unit dosages.

38. The kit of claim 37, wherein the composition further consists of a local anesthetic.

39. The kit of claim 37, wherein the NO donor is nitrous oxide.

40. The kit of claim 37, wherein the composition further consists of a corticosteroid.

41. The kit of claim 37, wherein the semisolid is selected from the group consisting of lotions, ointments, creams, and gels.

42. The kit of claim 37, wherein the kit further comprises an applicator.
43. The kit of claim 38, wherein the unit dosage is in an amount about 0.05 mg.
44. The kit of claim 38, wherein the unit dosage is in an amount from about 1.7 to about 3.5 mg.
45. The kit of claim 38, wherein the unit dosage is in an amount from about 2 to 5 mg.
46. An analgesic composition comprising nitroglycerin and sucralfate.
47. An analgesic composition comprising nitroglycerin, lidocaine and sucralfate.
48. An analgesic composition comprising nitroglycerin and sucralfate in an ointment or cream base.
49. An analgesic composition comprising nitroglycerin, lidocaine and sucralfate in an ointment or cream base.
50. A method for treating painful conditions of an anal region comprising: providing a composition comprising nitroglycerin and sucralfate; and applying an effective dose of the composition to the anal region.
51. A method for treating painful conditions of an anal region comprising: providing a composition comprising nitroglycerin, lidocaine and sucralfate; and applying an effective dose of the composition to the anal region.--

REMARKS

New claims 37-51 have been introduced by this preliminary amendment to the above-referenced patent application to more particularly set forth the present invention. Claims 46-51 have been added to copy the independent claims from U.S. Patent No. 6,159,944 (the "944 patent") to Fogel, issued December 12, 2000, from U.S. Application Serial No. 09/031,858, filed Feb. 27, 1998.

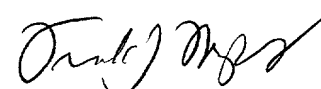
The subject matter of new claims 46-51 corresponds exactly to the independent claims of the '944 patent thusly:

Claim	'944 claim
46	1
47	2
48	5
49	6
50	8
51	9

Applicants note that 35 U.S.C. §135(b) requires a claim in an application of an issued patent be made prior to one year from the date the patent was granted. Support for the foregoing newly presented claims can be found in the specification and claims as filed.

Early action on the merits is respectfully solicited.

Respectfully submitted,



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Remarks

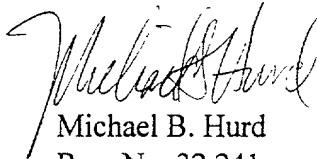
The remaining original claim has been cancelled and claims directed to the composition in an applicator and in a suppository form have been added. Support for these claims can be found in the specification, such as at page 17, lines 2-7:

For example, an ointment composition of the invention can be applied topically at each application to the external anus and to the distal anal canal with the finger or an applicator. As an illustrative alternative, the medication can be delivered intra-rectally as a suppository. (emphasis added)

The title has been amended in view of the cancellation of the method claims.

Examination and allowance of the claims are respectfully requested.

Respectfully submitted,

  
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November 14, 1997

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